

THE EFFECTS OF INNOVATIVE CHANGES TO
RESTAURANT INSPECTION PROTOCOLS

by

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ABSTRACT

The purpose of this study was to examine the effectiveness of health department interventions and procedures in reducing the occurrence of specific critical violations identified during routine restaurant inspections. Interventions included in the analysis were internet posting of restaurant inspection results, announced routine inspections and follow-up inspections.

This study uses a longitudinal analysis of inspection results from restaurant inspections conducted by the Salt Lake Valley Health Department between January 1, 2008 and April 30, 2011. Bivariate methods were used to assess the changes in the proportion of inspections during which the restaurant was cited for the target critical violations.

The occurrence of five specific, FDA defined, critical violations were included as outcome measures: poor hygiene practices, improper holding temperatures, inadequate equipment cleanliness, lack of protection from cross-contamination, and improper sanitizer concentration.

The probability of having a violation decreased in routine inspections conducted after the website launch when adjusted for inspector experience, risk level and seasonality. The adjusted odds ratios, ranging from 0.64 to 0.80, were statistically significant for all critical violations, with the exception of cross-contamination which was

borderline significant ($p=0.053$). The largest effect was found in equipment cleanliness violations (aOR=0.64).

Announced inspections were associated with significant reduction in the odds of personal hygiene (aOR=0.11, $p=0.00$) and equipment cleanliness (aOR=0.19, $p=0.00$) violations after adjusting for food type, visible kitchen, outside quality assurance, season and standardized inspector.

An assessment of follow-up inspections revealed the proportion of inspections with a violation was greater among those restaurants which had a previous follow-up inspection as compared to those inspections that did not have a previous follow-up inspection (range of difference = 6.98% – 22.46%) for each of the five critical violations. The risk of having a violation increased for all targeted critical violations during inspections conducted after a follow-up inspection compared to restaurant inspections without a prior follow-up, when adjusting for restaurant type, inspector experience and season. The adjusted odds ratios were significant for all target violations (aOR range = 1.67 – 1.96) with the largest odd ratios associated with personal hygiene violations (aOR = 1.96, $p<0.001$).

For my family – the focus of all I do

And especially Tina for your love, support and confidence

TABLE OF CONTENTS

ABSTRACT.....	iii
ACKNOWLEDGMENTS.....	vii
Chapters	
1. INTRODUCTION.....	1
2. IMPACT OF INTERNET POSTING OF RESTAURANT INSPECTION SCORES ON CRITICAL VIOLATIONS.....	5
2.1 Abstract.....	5
2.2 Introduction.....	6
2.3 Methods.....	8
2.4 Results.....	11
2.5 Discussion.....	14
2.6 References.....	17
3. EXAMINATION OF THE ASSOCIATION BETWEEN ANNOUNCED INSPECTIONS AND INSPECTION SCORES.....	19
3.1 Abstract.....	19
3.2 Introduction.....	20
3.3 Methods.....	23
3.4 Results.....	25
3.5 Discussion.....	31
3.6 References.....	36
4. EXAMINATION OF THE ASSOCIATION BETWEEN ROUTINE INSPECTION SCORES AND FOLLOW-UP INSPECTIONS.....	38
4.1 Abstract.....	38
4.2 Introduction.....	39
4.3 Methods.....	42
4.4 Results.....	44
4.5 Discussion.....	48
4.6 References.....	50
5. CONCLUSION.....	51

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CHAPTER 1

INTRODUCTION

Preventing foodborne illness is an important public health issue (U.S. Food and Drug Administration, 2005). Foodborne diseases result in 9.4 million illnesses, 55,961 hospitalizations and 3,151 deaths annually in the United States (Scallan, Hoekstra, & Angulo, 2011). The annual economic cost of foodborne illness is estimated to be \$152 billion (Scharff, 2010). In 2008 the projected incidence rate for all reported foodborne illnesses in the United States was 40.22 per 100,000 population (Centers for Disease Control and Prevention, 2009). The estimated incidence in Salt Lake County for the same time period was 36.67 per 100,000.

Prior to 2004 significant declines in specific foodborne illnesses were documented, however since that time progress toward the national health objective targets of reducing foodborne pathogen caused infections and foodborne illness outbreaks has stalled (Centers for Disease Control and Prevention, 2009). The incidence of STEC 0157 (Ecoli 0157) has dropped below targeted levels, but other pathogens have shown less progress (Centers for Disease Control and Prevention, 2011). The Centers for Disease Control and Prevention (CDC) has stated new approaches to food safety will be required to meet the Healthy People objectives (Centers for Disease Control and

Prevention, 2008). In a 2004 report, the Food and Drug Administration (FDA) called for more innovative and effective strategies to improve food safety practices in retail food establishments (U.S. Food and Drug Administration, 2004).

State and local health departments are responsible for regulating food safety in restaurants and implementing those new and innovative strategies. Health departments have relied primarily on training and inspections to ensure proper food handling behavior. Studies have shown that improving food safety practices, resulting in better inspection scores, reduces risk and improves public health (Buchholz, Fielding, Mascola, Run, & Kool, 2002; Irwin, Ballard, Grendon, & Kobayashi, 1989).

The purpose of this study is to evaluate the effectiveness of three practices for reducing critical violations; implementation of a restaurant inspection website through which Salt Lake Valley Health Department (SLVHD) posts scores and inspection results, announced routine inspections, and follow-up inspections.

Outcome measures used in this study were the five most frequently cited critical violations in Salt Lake County during 2007. These include 1) poor personal hygiene, 2) contaminated food contact surfaces, 3) holding temperatures not in safe range, 4) inadequate separation of foods to avoid cross-contamination and 5) improper sanitizer or chemical concentration.

The first intervention was the implementation of an inspection website on April 27, 2009 through which inspection scores, results and comments may be accessed. The website (<https://public.cdpehs.com/UTEnvPbl/ESTABLISHMENT/WelcomePage.aspx>) provides the public with pertinent information when selecting a restaurant and includes a restaurant ranking system based on inspection results, information regarding the number

of critical and noncritical violations by restaurant and closures due to violations.

Inspection data is available from 2008 to current.

The second intervention was a prospective randomized study of announced inspections which began January 1, 2010. The study included Risk Level 4 restaurants (full service) that were divided into two groups. One group received announced inspections and the other group was inspected on an unannounced schedule. Secondary data generated by the SLVHD study were analyzed to determine the effect of announced inspections on inspection scores and critical violations.

Follow-up inspections after a restaurant has been closed because of an imminent public health threat is a standard procedure. Standard 3 of FDA's Program Standards states programs must demonstrate "credible follow-up for each violation noted during an inspection" with emphasis placed on the foodborne illness risk factors. Standard 3 requires programs develop a program that requires follow-up activities (U.S. Food and Drug Administration, 2011). Assessing the long-term impact of such practices is the third component of this study.

The risk of foodborne illness is increasing due to the growing global market, the aging population, and increased numbers of immunocompromised and immunosuppressed individuals (U.S. Food and Drug Administration, 2005). Effective strategies are required to address the problem. The strategies evaluated in this study may provide regulators with additional tools for improving food safety in retail establishments.

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CHAPTER 2

IMPACT OF INTERNET POSTING OF RESTAURANT INSPECTION SCORES ON CRITICAL VIOLATIONS

Abstract

Posting restaurant inspection scores on the internet as a tool for improving food safety is becoming more common. Studies have been conducted evaluating the effectiveness of posting restaurant inspection scores in windows, however there has not been an evaluation of the association between posting scores on the internet and restaurant inspection results. The purpose of this study was to evaluate the association between internet posting of restaurant inspection scores and the five most frequently cited critical violations in Salt Lake County, Utah. The study examined 2,995 inspections conducted at 796 full service and fast food restaurants for a 1 year period before and after launch of a restaurant inspection website. Data in the retrospective, longitudinal study were analyzed using a generalized estimating equation (GEE). Critical violations decreased significantly after the website launch compared to before launch levels. The greatest improvements were found in temperature holding violations (odds ratio=0.75, $p<0.001$), hygiene practices violations (odds ratio=0.68, $p<0.001$) and equipment cleanliness violations (odds ratio=0.58, $p<0.001$). Restaurant type (full service, fast

food), inspector experience and season were significantly associated with the decrease in violations. Equipment cleanliness, cross-contamination and sanitizer concentration violations decreased significantly within 0 to 60 days after the website launch compared to before launch inspections. Holding temperature and personal hygiene violations decreased in the 61 to 180 days after launch. Holding temperature, personal hygiene and equipment cleanliness were significantly lower up to 1 year after launch compared to before launch inspections.

Introduction

Foodborne diseases result in 9.4 million illnesses, 55,961 hospitalizations and 3,151 deaths annually in the United States (Scallan, Hoekstra, & Angulo, 2011). One in six Americans suffer from foodborne illness each year (Scallan, et al., 2011). In 2008 the projected incidence rate for all reported foodborne illnesses in the United States was 40.22 per 100,000 population (CDC, 2009). The estimated incidence for the same time period was 36.67 per 100,000 in Salt Lake County.

Most foodborne illnesses can be linked to improper food handling practices. State and local health departments are responsible for regulating food safety in restaurants. Health departments rely on training and inspections to ensure proper food handling behavior and reduce the risk of foodborne illness outbreaks. These two procedures have not proven effective in creating long term behavioral compliance (Simon, Leslie, & Run, 2005). In response the United States Food and Drug Administration (FDA) has called for more innovative and effective strategies to improve food safety practices in retail food

establishments (Green, 2008; Mitchell, Fraser, & Bearon, 2007; United States Food and Drug Administration, 2004).

Studies have examined the association between inspection scores and foodborne illnesses with varying results (Buchholz, Run, Kool, Fielding, & Mascola, 2002; Cruz, Katz, & Suarez, 2001; Irwin, Ballard, Grendon, & Kobayashi, 1989; Jones, Pavlin, LaFleur, Ingram, & Schaffner, 2004; Penman & Webb, 1996). Studies conducted in Seattle-King County, Washington, and Los Angeles County, California concluded that inspection scores can identify restaurants with increased risk of foodborne illness outbreaks. The Seattle-King County study identified overall inspection scores, improper heating, cooling and storage temperatures and improper storage and handling of equipment as being associated with foodborne illness outbreaks (Irwin, et al., 1989). A study in California compared restaurants associated with foodborne illness outbreaks with previous inspections and found a lower inspection score to be predictive of foodborne illnesses (Buchholz, et al., 2002).

In contrast, studies conducted in Miami-Dade County, Florida, Tennessee and Alabama concluded restaurant scores alone are not predictive of future foodborne illness in a given restaurant. The Miami-Dade County study found 45% of restaurants associated with foodborne illness outbreaks had no critical violations cited during the most recent inspection (Cruz, et al., 2001). The Tennessee study compared scores from inspections conducted prior to foodborne disease outbreaks to all other inspections and found no significant difference (Jones, et al., 2004). A study in Alabama linked two foodborne illness outbreaks to restaurant inspections and found the inspections were ineffective in preventing outbreaks (Penman & Webb, 1996).

Public posting of inspection scores is thought to increase compliance through consumer pressure. In the only study of the impact of public posting, foodborne illness related hospital admissions in Los Angeles, California decreased 20% after implementation of restaurant window postings of inspection scores (Jin & Leslie, 2003; Simon, et al., 2005). The study compared inspection results of 13,544 restaurants between January 1, 1996 to December 31, 1998 to foodborne illness hospital admissions before and after the ordinance requiring window posting of inspection scores.

Municipalities nationwide have begun posting inspection scores on the internet to improve the accessibility of scores to the public; however the efficacy of internet postings is unknown. A search of PubMed and EBSCOhost databases yielded no papers examining the impact of internet access to inspection scores on subsequent scores or foodborne illness outbreaks.

On April 23, 2009 the Salt Lake Valley Health Department (SLVHD) launched a website that provides restaurant inspection results, scores, rankings, and restaurant closure information (<https://public.cdpehs.com/UTEnvPbl/ESTABLISHMENT/>). The purpose of this study is to evaluate the website's impact on subsequent inspection results.

Methods

Study design

This study uses a longitudinal analysis of inspection results. Study data were limited to routine inspections performed by licensed environmental health specialists at full service and fast food restaurants in Salt Lake County, Utah. Inspections conducted 12 months before and after the website launch were included. Only those restaurants which

were inspected at least twice before and twice after launch were included in the study. A total of 2,995 inspections conducted at 795 restaurants were evaluated.

Outcomes

The occurrence of five specific, FDA defined, critical violations were included as outcome measures: poor hygiene practices (lack of handwashing and eating, drinking or using tobacco in the food preparation area), improper holding temperatures (hot and cold holding temperature citations), inadequate equipment cleanliness (dirty equipment, utensils or food contact surfaces), lack of protection from cross-contamination (food separation, packaging and segregation citations), and improper sanitizer concentration (improper manual and mechanical ware washing chemical sanitizer levels). These are referred to as ‘target critical violations’. These violations were selected because they were included in the domains identified by the FDA as “most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks” (U.S. Food and Drug Administration, 2004).

Statistical Analysis

Univariate and bivariate methods were used to assess the changes in the proportion of inspections during which the restaurant was cited for the target critical violations before and after the launch of the website.

Multivariable methods were used to assess the changes in inspection results. Logistic regression using a Generalized Estimating Equation (GEE) were used to account for the repeated measures from each restaurant. The outcome variables were each

dichotomous indicating whether the restaurant was cited for that type of critical violation.

A first order autoregressive (AR1) correlation structure was assumed to account for any correlation between the previous and current inspection. Based on the quasi-likelihood criteria, the AR1 structure performed as well as other correlation structures. Odds ratios were used to describe the effect of the intervention. Data were analyzed using STATA software version 9 (College Station, Texas).

Models were adjusted for restaurant type (full service compared to fast food), inspector experience and season. Experienced inspectors were defined as those who conducted 200 or more inspections during the study period. Season was grouped into four 3 month periods: Summer (June, July, August), Fall (September, October, November), Winter (December, January, February), Spring (March, April, May).

Two different model specifications were used to assess the changes in violation frequency associated with the intervention launch. The first set of models used a single indicator variable to denote whether the inspection occurred before or after the launch date. To account for the potential attenuation of the effect of the website over time, or a delay in its impact, a second set of models were run using indicator variables delineating three time periods after the launch. The attenuation analysis compared before launch inspections with those conducted 0–30 day after launch, 31–60 day after launch, 61–180 days after launch and 181–365 after launch.

Results

The final dataset included 2,995 inspections conducted at 796 restaurants with an average of 3.8 inspections per restaurant (range = 1–8). Distributions of the number of inspections by the explanatory variable are presented in Table 2.1.

The proportion of inspections with any of the targeted violations was lower during the twelve months after the launch compared to before the launch (Table 2.2). The difference in proportions ranged from 2.07 (cross-contamination) to 8.99 (equipment cleanliness).

Table 2.1. Distribution of inspections by season, inspector experience and before and after launch, number and percentage (%)

	Before launch n (%)		After launch n (%)	
Season				
Winter	206	(14.60)	323	(20.39)
Spring	371	(26.29)	365	(23.04)
Summer	416	(29.48)	444	(28.03)
Fall	418	(29.62)	452	(28.54)
Experienced Inspector				
Yes	593	(42.03)	631	(39.84)
No	818	(57.97)	953	(60.16)
Restaurant Type				
Full Service	525	(37.21)	580	(36.62)
Fast food	886	(62.79)	1004	(63.38)
Total	1411	(47.11)	1584	(52.89)

Table 2.2. Change in percentage of inspections with violations before and after website launch

Critical Violation	Number of Inspections with Violations		Percent. Of Insp with Violations		Change (% points)	P-value (difference)
	Before	After	Before	After		
Equipment Cleanliness	461	376	32.67	23.68	-8.99	<0.001
Holding Temperature	457	456	32.39	28.71	-3.68	<0.001
Hygiene Practices	412	348	29.20	21.91	-7.29	<0.001
Cross-contamination	175	164	12.40	10.33	-2.07	0.018
Sanitizer Concentration	125	104	8.86	6.55	-2.31	0.013
Other Critical	624	635	44.22	39.99	-4.23	<0.001

Before / After Model Results

The probability of having a violation decreased in routine inspections conducted after the website launch when adjusted for inspector experience, risk level and seasonality (Table 2.3). The adjusted odds ratios, ranging from 0.64 to 0.80, were statistically significant for all critical violations, with the exception of cross-contamination which was borderline significant ($p=0.053$). The largest effect was found in equipment cleanliness violations (aOR=0.64).

Full service restaurants were more likely to be cited for all of the targeted critical violations than fast food facilities, with adjusted odds ratios ranging from 1.43 ($p=0.015$) in sanitizer concentration to 2.12 ($p=0.000$) in hygiene violations. Inexperienced inspectors were significantly more likely to cite personal hygiene, equipment cleanliness, cross-contamination and sanitizer concentration violations compared to experienced inspectors. Holding temperature violations, however were more likely to be cited by experienced inspectors. The effect of season varied by the critical violation being examined. The odds of being cited for holding temperature, hygiene, and equipment cleanliness violations were lower in all seasons compared to summer. The odds of violation increased in all seasons compared to summer for cross-contamination and sanitizer concentration violations with the exception of inspections citing sanitizer concentration violations conducted in spring which showed a slight, insignificant decrease.

Table 2.3. The effect of internet posting of restaurant inspection results on specific critical violations by before and after launch, restaurant type, season and inspector experience

	Holding Temp. Odds Ratio (p)	Hygiene Odds Ratio (p)	Equipment Odds Ratio (p)	Cross Contamin. Odds Ratio (p)	Sanitizer Odds Ratio (p)
After vs. Before	0.80 (0.009)	0.68 (0.000)	0.64 (0.000)	0.79 (0.053)	0.73 (0.024)
Before = referent group					
Restaurant Risk Level					
Full Service v. Fast Food	2.12 (0.000)	1.81 (0.000)	1.77 (0.000)	1.69 (0.000)	1.43 (0.015)
Fast Food = referent					
Season					
Fall vs. Summer	0.66 (0.000)	0.89 (0.346)	0.72 (0.008)	1.25 (0.213)	1.23 (0.325)
Winter vs. Summer	0.74 (0.005)	0.82 (0.101)	0.60 (0.000)	1.36 (0.068)	1.28 (0.213)
Spring vs. Summer	0.57 (0.000)	0.76 (0.026)	0.69 (0.001)	1.13 (0.507)	0.71 (0.134)
Summer = referent group					
Experienced Inspector	0.92 (0.37)	1.32 (0.003)	1.75 (0.000)	1.44 (0.004)	1.46 (0.009)
Experienced = referent group					
Wald Chi2	89.78 (0.0000)	72.29 (0.0000)	111.98 (0.0000)	34.34 (0.0000)	55.52 (0.0000)
Attenuation					
Before launch = referent group					
Before launch vs 0-60 Days Post	0.88 (0.403)	0.75 (0.145)	0.71 (0.024)	0.56 (0.024)	0.52 (0.058)
Before launch vs. 61-180 Days Post	0.71 (0.008)	0.67 (0.005)	0.71 (0.011)	0.71 (0.103)	0.57 (0.027)
Before launch vs.181-365 Days Post	0.80 (0.019)	0.64 (0.000)	0.58 (0.000)	0.94 (0.650)	0.79 (0.149)
Restaurant Risk Level					
Full Service v. Fast Food	2.09 (0.000)	1.77 (0.000)	1.84 (0.000)	1.66 (0.000)	1.47 (0.013)
Fast Food = referent					
Season					
Fall vs. Summer	0.65 (0.001)	0.90 (0.149)	0.75 (0.029)	1.19 (0.383)	1.11 (0.628)
Winter vs. Summer	0.72 (0.013)	0.84 (0.218)	0.64 (0.001)	1.16 (0.464)	1.20 (0.449)
Spring vs. Summer	0.54 (0.000)	0.76 (0.046)	0.75 (0.032)	1.09 (0.690)	0.73 (0.200)
Summer = referent group					
Experienced Inspector	0.90 (0.281)	1.36 (0.001)	1.72 (0.000)	1.41 (0.008)	1.39 (0.026)
Experienced = referent group					
Wald Chi2	80.16 (0.0000)	70.09 (0.0000)	111.58 (0.0000)	34.31 (0.0000)	33.07 (0.0000)

Attenuation Model Results

The effect of the website increased over time from launch for three of the critical violations: holding temperature, personal hygiene and equipment cleanliness. The odds ratios for holding temperatures and personal hygiene were nonsignificant in the first 60 days after launch, but were significant for the time periods after 60 days.

Cross-contamination and sanitizer concentration violations had an opposite trend in which the odds ratios increased in all time periods after launch. Significant odds ratios were identified in the first 60 days after launch but became insignificant over time.

Restaurant type, season and inspector experience in the attenuated model were very similar to the odds ratios in the before / after model.

Discussion

The implementation of a web-based system for public access to restaurant inspection results appears to have had some impact on the frequency of critical violations noted by inspectors. The odds ratios for all of the five violations examined in this study indicate citations reduced significantly after the website launch compared to before launch when adjusted for restaurant type, season and inspector experience. The effects were observed for all five critical violations studied, with a sustained effect (>180 days) observed for critical violations of holding temperatures, hygiene and equipment cleanliness. Based on these results, implementing such a web-based system may lead to a 20 to 30 % reduction in the number of inspections with these critical violations.

Full service restaurants had significantly higher odds of being cited for violations than fast food restaurants in all of the targeted critical violations. This may be due to the

complex menus and processes found in full service restaurants and the protocols established by some fast food chain restaurants.

Season appears to affect critical violations differently. The largest effects were in temperature holding violations in all seasons compared to summer. The odds of inspections with holding temperature violations increased between 26% and 43% in the summer months compared to other seasons. This may be due to cooling units malfunctioning during periods of high ambient temperature. Equipment cleanliness and personal hygiene violations were also reduced in other seasons compared to summer possibly due to an untrained temporary summer workforce storing personal drinks in the food preparation area during hot temperatures and a general lack of attention to cleaning detail. Hygiene practices violations reduced significantly in spring compared to summer, but differences in other seasons were insignificant.

To our knowledge, this is the first published study assessing the impact of such a web-based system. These results are similar to the results of previous studies which examined the effect of posting restaurant inspection scores at the restaurant. In a study conducted in Los Angeles, California foodborne illness related hospital admissions decreased 20% after implementation of restaurant window postings of inspection scores (Jin & Leslie, 2003; Simon, et al., 2005).

The study was limited by the available data. Factors that may have been associated with the frequency of violations include the type of food served and serving style (e.g., buffet compared to individual plate), the level of experience of the workers and management, and the 'culture' and beliefs of the workers about the importance of good food handling practices.

However the study did control for major predictors such as season, the level of experience of the inspector, and whether the restaurant was full service or 'fast food.' Further, the study included virtually all 'sit down' restaurants in Salt Lake County, Utah, although this limits the generalizability of the findings. Given the magnitude of the results, it seems unlikely that the results are an artifact of uncontrolled confounding.

The occurrence of foodborne outbreaks are the primary public health concern. However this was not used due to the small number of observed outbreaks, and under-reporting. Violation codes have been recommended as proxy measures to determine food safety, and are the focus of regulatory efforts (U.S. Food and Drug Administration, 2009). As such, the occurrence of these critical violations as the outcome variables was appropriate.

While the study included inspections as much as 1 year from the launch of the website, it would be useful to continue to assess the temporal trends to see if the rates of violation return to the levels observed before the beginning of this effort. It may be necessary to conduct periodic efforts to remind the public about the website and highlight the importance of food safety to maintain the impact of the web access to inspection results. The average daily website hits have diminished over time. Within 1 hour of the press conference announcing the website, over 68,000 visitors had logged onto the site, temporarily crashing the system (Moore, 2009). Over one million hits were received within the first twenty four hours after launch. At the end of January 2011 the daily average number hits had dropped to 4,640.

SLVHD classifies restaurants according to risk level. Full service restaurants are part of the highest risk category and consequently are inspected three to four times

annually. This study confirms the risk level ranking and provides additional justification for the stated inspection frequency. Additional efforts should be directed at reducing the occurrence of critical violations in full service restaurants including active managerial controls and trainings. Studies identifying managerial attitudes are recommended to correctly identify effective interventions.

The impact of such an effort would certainly be expected to vary across locations. The results of this study suggest that such a program at least has the potential for improving some aspects of food safety in restaurants. Studies in other locations may help to identify the factors that are important for ensuring the success of such programs.

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CHAPTER 3

EXAMINATION OF THE ASSOCIATION BETWEEN ANNOUNCED INSPECTIONS AND INSPECTION SCORES

Abstract

In 2010 The Salt Lake Valley Health Department (SLVHD) conducted a pilot of an announced inspection program utilizing a randomized assignment of restaurants to an intervention group with announced inspections and a control group which remained on the usual schedule of unannounced inspections.

After adjusting for food type, visible kitchen, outside quality assurance, season and standardized inspector, significant reductions were found in the odds of personal hygiene (aOR=0.11, $p=0.00$) and equipment cleanliness (aOR=0.19, $p=0.00$) violations. In the models for the control group, none of the odds ratios were statistically different from one, indicating no change in the post-intervention time period as compared to the pre-intervention period.

Oriental food restaurants had significantly increased odds of being cited for a targeted violation compared to American restaurants, but this was only for cross-contamination violations (aOR=4.60, $p<0.01$) and sanitizer concentration violations (aOR=2.56, $p=0.07$). Restaurants with a visible kitchen were at a significantly lower risk

of cross-contamination violations compared to restaurants without a visible kitchen (aOR=0.24, $p=0.01$). Visible kitchens were also significantly more likely to be cited for any critical violation (aOR=0.51, $p=0.04$). Utilizing outside quality assurance reduced the odds of a cross-contamination violation (aOR=0.48, $p=0.06$), but had no significant effect with any of the other targeted violations.

The season in which the inspection was conducted had no significant association with any of the outcome measures with the exception of equipment cleanliness violations cited in fall compared to summer (aOR=0.51, $p=0.07$).

FDA standardized inspectors were twice as likely to cite holding temperature violations compared to nonstandardized inspectors (aOR=2.00, $p=0.02$), however the odds of a standardized inspector citing equipment cleanliness violations was about half of a non-standardized inspector (aOR=0.56, $p=0.04$).

Introduction

Foodborne diseases remain an issue in the United States. Each year 9.4 million cases of foodborne illness are acquired resulting in 55,961 hospitalizations and 1,351 deaths(Scallan, Hoekstra, & Angulo, 2011). The annual economic cost of foodborne illness is estimated to be \$152 billion(Scharff, 2010). In 2008 the projected incidence rate for all reported foodborne illnesses in the United States was 40.22 per 100,000 population (Centers for Disease Control and Prevention, 2010). The Centers for Disease Control and Prevention reported reductions in the incidence of shiga toxin-producing *E. coli* (STEC O157) and shigella infections, but little or no recent progress for other pathogens (Centers for Disease Control and Prevention, 2010). STEC O157 was the only target met in 2009

of the four infections with Healthy People 2010 targets (campylobacter, listeria, salmonella, and STEC O157).

Restaurant inspections have been a primary tool used by regulators to ensure good hygiene and food preparation practices and prevent foodborne illness; however the effectiveness of inspections in reducing foodborne illness risk factors is unclear (Jones, Pavlin, LaFleur, Ingram, & Schaffner, 2004). A review of PubMed and EBSCOhost Web databases revealed only a single study assessing the impact of announced inspections of restaurants on subsequent inspection results. This study focused on a program implemented by the Minneapolis Environmental Health Food Safety in 2007 (Reske, Jenkins, Fernandez, VanAmber, & Hedberg, 2007). The goal of this educational program was to provide restaurant operators with better information, tools and support to help them improve food safety practices and prevent foodborne illnesses. The primary innovation was the use of announced inspections alternating with regular unannounced inspections. Prior to the announced inspections inspectors conducted an in-depth interview with the person in charge to discuss the need to control foodborne illness risk factors. Each restaurant was subject to a second unannounced inspection within a 1 year period. Restaurants with ongoing problems were inspected more frequently. The study examined specific critical and noncritical violations including some included in the current study (holding temperatures, equipment cleanliness, and cross-contamination). The results of the Minnesota study indicated a 50% reduction the median number of critical violations cited during announced inspections compared to unannounced inspections.

While this is the only study of the impact of announced inspections for food service establishments, other regulatory agencies routinely use announced inspections. In 1998 the FDA initiated a new approach to enforcement in which announced inspections were used in regulating the medical device industry. Findings from the study indicate communications between the agency and industry improved, costs for both parties were reduced and regulated facilities demonstrated greater compliance with the regulations (U.S. Food and Drug Administration, 1997). The use of announced inspections of child care facility inspections in Pennsylvania resulted in a significant decrease in the number of citations (Fiene, 1996). Whether this reduction resulted in a decrease in the number of foodborne illnesses is unknown due to difficulties in reporting and monitoring outbreaks.

The FDA recently recommended regulatory agencies utilize “innovative and effective strategies to improve food safety practices in retail and foodservice establishments” to improve food safety practices in foodservice and retail food establishments (U.S. Food and Drug Administration, 2004). The CDC stated in 2010 that multifaceted approaches are required to reduce foodborne illnesses (Centers for Disease Control and Prevention, 2010a).

Little inspection guidance was provided to regulatory agencies until the U.S. Food and Drug Administration (FDA) began publishing the Food Code in 1993 which specified areas inspectors should monitor to protect consumer health including demonstration of knowledge, implementation of employee health policies, hands as a vehicle of contamination, time/temperature relationships and consumer advisories (U.S. Food and Drug Administration, 2009a). The FDA recommended agencies implement hazard analysis and critical control point (HACCP) inspections beginning in 2000 which

emphasized prioritization of inspections based on risk. This new approach was designed to prevent future violations from occurring rather than the reactive design of the traditional inspection process (U.S. Food and Drug Administration, 2009a).

In 2010 The Salt Lake Valley Health Department (SLVHD) conducted a pilot of an announced inspection program wherein restaurant owners and managers were notified one week prior to an inspection. This pilot program utilized a randomized assignment of restaurants to an intervention group with announced inspections and a control group which remained on the usual schedule of unannounced inspections. The purpose of this study was to assess the impact of this pilot program.

Methods

Study Design

Restaurants were randomly assigned by the SLVHD to either an intervention or a control group. The intervention group was inspected two times using a traditional, unannounced inspection followed by two announced inspections over the next 4 months. Dates for the announced inspections were set-up in advance so that managers or owners could be present. A second announced inspection was conducted approximately 2 months later. These inspections were carried out in the same manner as the usual unannounced inspections. Restaurants in the control group were subject to regular unannounced inspections carried out at the typical frequency of every three to four months. The study period was January 11, 2008 to May 6, 2010 with all announced inspections conducted between January 1, 2010 and May 6, 2010.

Outcome

The FDA recommends using the occurrence of foodborne illness risk factors (critical violations) as a measure of restaurant food safety (U.S. Food and Drug Administration, 2010b). Outcome variables in this study included the five most frequently cited critical violations in Salt Lake County – poor hygiene practices (lack of handwashing and eating, drinking or using tobacco in the food preparation area), improper holding temperatures (improper hot or cold holding temperature), unclean food equipment (dirty equipment, utensils, or food contact surfaces), failure to protect from cross-contamination (inadequate food separation, packaging, and segregation), and improper sanitizer concentration levels (improper manual and mechanical ware washing chemical sanitizer levels). These variables are included in FDA's list of risk factors as violations which are most likely to lead to foodborne illness.

Statistical Analysis

Changes in the frequency of specific critical violations between pre- and post-intervention inspections were evaluated using univariate and multivariable methods. Two types of multivariable models were employed. First, stratified models were used whereby the effect of the pre- and postintervention was estimated separately for the intervention and control groups. The second model incorporated all observations, using variables indicating group (intervention compared to control) and time period (pre- compared to postintervention). An interaction term was included to assess the differences between the pre- and postintervention periods for each group separately. Generalized Estimating

Equations (GEE) were used to estimate the parameters because repeated measures were collected on the same establishment over time. The models used a logit function, binomial family and a first order autoregressive (AR1) correlation structure. Odds ratios were used to describe the effect of the intervention. Data analysis was conducted using STATA® software version 9 (College Station, Texas).

The models included variables describing kitchen visibility, primary food type, the use of a third party quality assurance company, standardized inspector, and calendar season. A ‘visible kitchen’ was defined as a kitchen which is visible from the dining area, based on the observation of the inspector. Restaurants were classified as to the primary type of food served: American, Mexican, Oriental, Mediterranean, and other. Third-party quality assurance refers to the use of a quality assurance entity from outside the restaurant management. Standardized inspectors was defined as an inspector who had met the FDA standardization protocol which requires completion of specific FDA courses and field activities (U.S. Food and Drug Administration, 2011). Season was defined as summer (June, July, August), fall (September, October, November), winter (December, January, February), spring (March, April, May).

Results

A total of 122 restaurants were included in the study; the intervention group consisted of 63 restaurants and the control group included 59 establishments. Each restaurant was inspected four times during the study period for a total of 488 inspections (Table 3.1).

Before the intervention the proportion of inspections with each violation was similar in the control and interventions groups (Table 3.2 and Figure 3.1). In the intervention group the proportion of inspections with violations declined significantly after the intervention for personal hygiene violations, equipment cleanliness violations, cross-contamination violations, and any critical violations. In contrast, there were no statistically significant decreases in the proportion of inspections in the control group. Hygiene, equipment cleanliness, cross-contamination, and sanitizer concentration violations decreased or remained level postintervention in unannounced inspections.

In the stratified multivariable models for the intervention group, both the unadjusted and adjusted odds ratios for having a critical violation during an announced inspection as compared to the unannounced interventions were significantly lower for personal hygiene violations (OR=0.23, $p<0.01$), equipment cleanliness violations (OR=0.33, $p<0.01$) and any critical violation (OR=0.21, $p<0.01$) (Table 3.3). The reduction in violations for cross-contamination was no longer significant. After adjusting for food type, visible kitchen, outside quality assurance, season and standardized inspector, the significant reductions in the odds of personal hygiene (aOR=0.11, $p=0.00$) and equipment cleanliness (aOR=0.19, $p=0.00$) violations remained. In the models for the control group, none of the odds ratios were statistically different from one, indicating no change in the post-intervention time period as compared to the preintervention period.

The interaction model yielded similar results, although the ORs for poor hygiene and equipment cleanliness violations were somewhat attenuated (Table 3.4). In addition, the odds of being cited for an equipment cleanliness violation had a moderately significant decrease in the control group (aOR=0.54, $p=0.08$). There was a marginally

significant reduction in equipment cleanliness violations among restaurants in the control group after the announced inspections were implemented as compared to the time period before the intervention; but there were no other significant changes in any of the other violations in the control group. In the post-intervention period, there were significant differences in the odds of a violation for personal hygiene violations (aOR=0.33, $p=0.03$) and any critical violation (aOR=0.47, $p=0.04$), but not for the other types of violations.

Table 3.1 Inspection distribution by pre/postintervention and announced/unannounced inspection type

	Preintervention	Postintervention	Total
Intervention Group	126	126	252
Control Group	118	118	236
Total	244	244	488

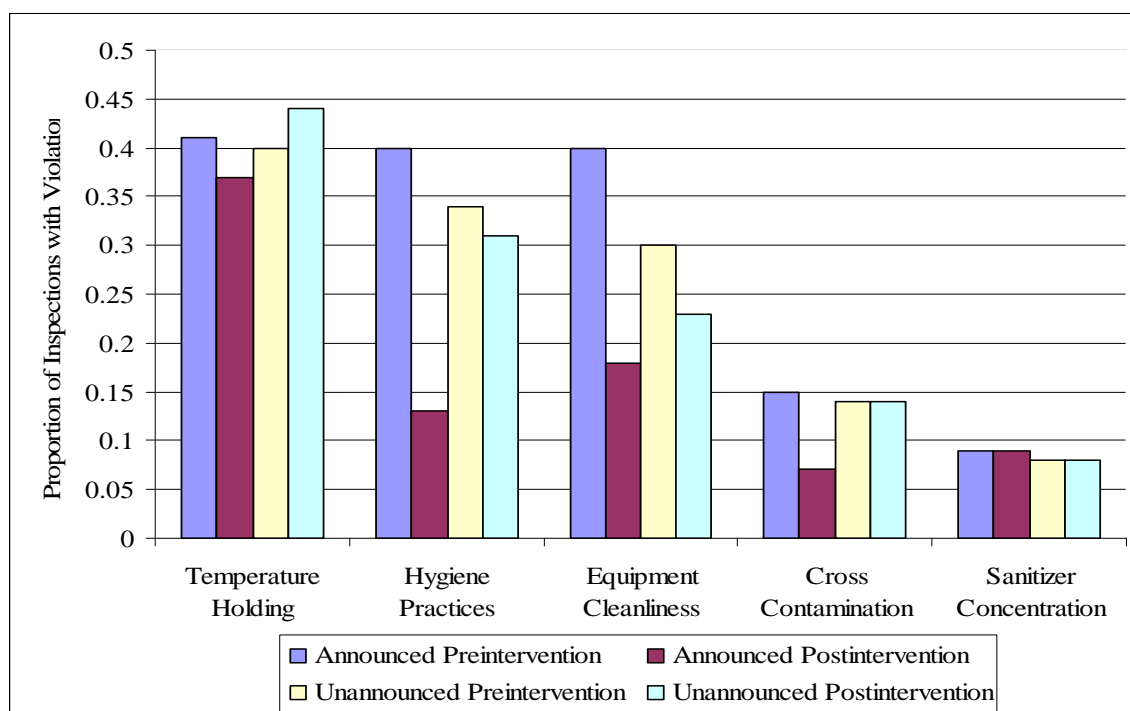


Figure 3.1 Proportion of inspections with violation, pre and postintervention by violation

Table 3.2 Proportion of inspections with violation by target violation and all critical violations

	Preintervention Proportion (n with violation)	Intervention Proportion (n)	Change	P-value (CI) <i>p</i> , (95%CI)
Temperature Holding				
Intervention	0.41 (51)	0.37 (46)	-0.04	0.52 (-0.16, 0.08)
Control	0.40 (47)	0.44 (52)	0.04	0.51 (-0.08, 0.17)
Hygiene Practices				
Intervention	0.40 (50)	0.13 (16)	-0.27	0.00 (0.17, 0.37)
Control	0.34 (40)	0.31 (36)	-0.03	0.58 (-0.09, 0.15)
Equipment Cleanliness				
Intervention	0.40 (50)	0.18 (22)	-0.22	0.00 (-0.33, -0.11)
Control	0.30 (35)	0.23 (27)	-0.07	0.24 (-0.18, 0.45)
Cross-Contamination				
Intervention	0.15 (19)	0.07 (9)	-0.08	0.05 (-0.16, 0.00)
Control	0.14 (17)	0.14 (16)	0	0.85 (-0.10, 0.08)
Sanitizer Concentration				
Intervention	0.09 (11)	0.09 (12)	0	0.83 (-0.06, 0.08)
Control	0.08 (9)	0.08 (10)	0	0.81 (-0.06, 0.08)
Any Critical				
Intervention	0.94 (118)	0.75 (94)	-0.19	0.00 (0.80, 0.89)
Control	0.81 (95)	0.85 (100)	0.04	0.39 (0.78, 0.88)

Table 3.3 Adjusted and unadjusted odds ratios of having a critical violation after the intervention

	Personal Hygiene OR (<i>p</i> -value)	Holding Temperature OR (<i>p</i> -value)	Equipment Cleanliness OR (<i>p</i> -value)	Cross- contamination OR (<i>p</i> -value)	Sanitizer Concentration OR (<i>p</i> -value)	Any Critical Violation OR (<i>p</i> -value)
Unadjusted						
Intervention Group	0.23 (0.00)	0.84 (0.50)	0.33 (0.00)	0.43 (0.19)	1.12 (0.80)	0.21 (0.00)
Control Group	0.86 (0.61)	1.21 (0.47)	0.71 (0.30)	0.81 (0.60)	1.13 (0.81)	1.43 (0.31)
Adjusted*						
Intervention Group	0.11 (0.00)	1.03 (0.93)	0.19 (0.00)	0.66 (0.45)	1.04 (0.95)	0.20 (0.02)
Control Group	0.72 (0.41)	0.64 (0.24)	0.64 (0.28)	1.53 (0.53)	0.74 (0.65)	0.75 (0.59)

*Adjusted for restaurant type, primary cuisine, inspector certification, and season.

Table 3.4 Adjusted odds ratios by violation type

	Hygiene	Temperature	Equipment	Cross-Contam.	Sanitizer	Any Critical
	OR (p-value)	OR (p-value)	OR (p-value)	OR (p-value)	OR (p-value)	OR (p-value)
Intervention Group: Announced vs. unannounced(referent)	0.16 (0.00)	0.66 (0.21)	0.26 (0.00)	0.66 (0.45)	0.86 (0.78)	0.12 (0.00)
Control Group: Post- vs. preintervention(referent)	0.61 (0.15)	1.03 (0.93)	0.54 (0.08)	1.46 (0.46)	0.88 (0.83)	0.90 (0.83)
Post-intervention: Intervention vs. Control (referent)	0.33 (0.03)	0.72 (0.24)	0.71 (0.31)	0.45 (0.08)	1.07 (0.88)	0.47 (0.04)
Food type (American = referent group)						
Mexican	1.73 (0.11)	0.95 (0.86)	1.26 (0.50)	1.74 (0.17)	1.12 (0.83)	1.56 (0.34)
Oriental	1.06 (0.90)	1.11 (0.78)	1.55 (0.27)	4.60 (0.00)	2.58 (0.07)	2.23 (0.25)
Mediterranean	0.58 (0.24)	0.79 (0.52)	1.03 (0.95)	0.20 (0.14)	1.21 (0.76)	0.82 (0.68)
Other	2.18 (0.28)	0.71 (0.63)	2.00 (0.30)	2.14 (0.30)	2.26 (0.35)	0.79 (0.81)
Kitchen Visible from Dining (No = referent)	1.10 (0.75)	1.02 (0.91)	0.83 (0.51)	0.24 (0.01)	0.45 (0.13)	0.51 (0.04)
Outside Quality Assurance (No = referent)	0.79 (0.37)	1.02 (0.90)	0.83 (0.45)	0.48 (0.06)	0.99 (0.98)	0.64 (0.14)
Season (Summer = referent)						
Fall	0.74 (0.40)	0.98 (0.95)	0.51 (0.07)	2.29 (0.14)	0.69 (0.56)	0.84 (0.74)
Winter	1.59 (0.21)	1.05 (0.90)	1.49 (0.31)	0.99 (0.99)	1.15 (0.82)	2.00 (0.22)
Spring	0.85 (0.67)	0.92 (0.83)	1.12 (0.77)	1.01 (0.99)	0.61 (0.45)	0.77 (0.63)
Standardized Inspector (No = referent)	1.22 (0.50)	2.00 (0.02)	0.56 (0.04)	0.78 (0.53)	2.12 (0.21)	1.93 (0.10)
Wald Chi2	32.49 (0.002)	8.44 (0.814)	31.6 (0.003)	36.22 (0.000)	11.94 (0.532)	32.03 (0.002)

Oriental food restaurants were the only restaurant type with significantly increased odds of being cited for a targeted violation compared to American restaurants, but this was only for cross-contamination violations (aOR=4.60, $p<0.01$) and sanitizer concentration violations (aOR=2.56, $p=0.07$). Restaurants with a visible kitchen were at a significantly lower risk of cross-contamination violations compared to restaurants without a visible kitchen (aOR=0.24, $p=0.01$). Visible kitchens were also significantly more likely to be cited for any critical violation (aOR=0.51, $p=0.04$). Utilizing outside quality assurance reduced the odds of a cross-contamination violation (aOR=0.48, $p=0.06$), but had no significant effect with any of the other targeted violations.

The season in which the inspection was conducted had no significant association with any of the violations. Inspections conducted in the fall were moderately associated with a reduction in odds ratios for equipment cleanliness violations (aOR=0.51, $p=0.07$).

Standardized inspectors were twice as likely to cite holding temperature violations compared to nonstandardized inspectors (aOR=2.00, $p=0.02$). The odds of a standardized inspector citing equipment cleanliness violations was about half of a non-standardized inspector (aOR=0.56, $p=0.04$). Changes in the other violations were insignificant although the odds of standardized inspectors citing hygiene and sanitizer concentration violations were greater than nonstandardized inspectors.

Discussion

Announced restaurant inspections appear to improve some aspects of food safety. There was an 80 to 90% reduction in the odds of a critical violation for poor hygiene practices (e.g., lack of handwashing, personal food and drink in the food preparation

area), and a 70 to 80% reduction in the odds of a violation for inadequate equipment cleanliness (e.g., food contact surfaces and utensils are not clean or have an accumulation of grease). These results remained when controlling for other factors that might be associated with the issuance of a critical violation. In the models for these two critical violations, however, inspector experience and fall season (compared to summer) were the only significant predictors, and these were significant only in the equipment cleanliness model. Even though the announced inspections were not associated with significant reductions in any of the other types of critical violations, the point estimates were all less than one.

There was also a marginally significant reduction in the odds of an equipment cleanliness violation in the control group (preintervention time-period compared to post-intervention time period). Even so, the reduction observed for the intervention group ($aOR=0.26$, $p<0.01$) was much greater than the reduction observed in the control group ($aOR=0.54$, $p=0.08$), indicating an effect of the announced inspections.

The risk of receiving a cross-contamination citation was significantly lower post-intervention in the crude comparison, but not in the multivariate model. This may be due to the effect of Oriental restaurants on cross-contamination violations.

These results are generally consistent with a 2007 study conducted in Minneapolis which found a 50% reduction the median number of critical violations cited during announced inspections compared to unannounced inspections (Reske, et al., 2007). The SLVHD study differs from the Minneapolis study in several key areas. The restaurants in this study were randomized prior to the study into the intervention and control groups. The Minnesota study was a retrospective cohort study in which restaurants were

Table 3.4 Adjusted odds ratios by violation type

	Hygiene	Temperature	Equipment	Cross-Contam.	Sanitizer	Any Critical
	OR (p-value)	OR (p-value)	OR (p-value)	OR (p-value)	OR (p-value)	OR (p-value)
Intervention Group: Announced vs. unannounced(referent)	0.16 (0.00)	0.66 (0.21)	0.26 (0.00)	0.66 (0.45)	0.86 (0.78)	0.12 (0.00)
Control Group: Post- vs. pre-intervention(referent)	0.61 (0.15)	1.03 (0.93)	0.54 (0.08)	1.46 (0.46)	0.88 (0.83)	0.90 (0.83)
Post-intervention: Intervention vs. Control (referent)	0.33 (0.03)	0.72 (0.24)	0.71 (0.31)	0.45 (0.08)	1.07 (0.88)	0.47 (0.04)
Food type (American = referent group)						
Mexican	1.73 (0.11)	0.95 (0.86)	1.26 (0.50)	1.74 (0.17)	1.12 (0.83)	1.56 (0.34)
Oriental	1.06 (0.90)	1.11 (0.78)	1.55 (0.27)	4.60 (0.00)	2.58 (0.07)	2.23 (0.25)
Mediterranean	0.58 (0.24)	0.79 (0.52)	1.03 (0.95)	0.20 (0.14)	1.21 (0.76)	0.82 (0.68)
Other	2.18 (0.28)	0.71 (0.63)	2.00 (0.30)	2.14 (0.30)	2.26 (0.35)	0.79 (0.81)
Kitchen Visible from Dining (No = referent)	1.10 (0.75)	1.02 (0.91)	0.83 (0.51)	0.24 (0.01)	0.45 (0.13)	0.51 (0.04)
Outside Quality Assurance (No = referent)	0.79 (0.37)	1.02 (0.90)	0.83 (0.45)	0.48 (0.06)	0.99 (0.98)	0.64 (0.14)
Season (Summer = referent)						
Fall	0.74 (0.40)	0.98 (0.95)	0.51 (0.07)	2.29 (0.14)	0.69 (0.56)	0.84 (0.74)
Winter	1.59 (0.21)	1.05 (0.90)	1.49 (0.31)	0.99 (0.99)	1.15 (0.82)	2.00 (0.22)
Spring	0.85 (0.67)	0.92 (0.83)	1.12 (0.77)	1.01 (0.99)	0.61 (0.45)	0.77 (0.63)
Standardized Inspector (No = referent)	1.22 (0.50)	2.00 (0.02)	0.56 (0.04)	0.78 (0.53)	2.12 (0.21)	1.93 (0.10)
Wald Chi2	32.49 (0.002)	8.44 (0.814)	31.6 (0.003)	36.22 (0.000)	11.94 (0.532)	32.03 (0.002)

“scheduled to receive alternating announced and unannounced inspections” (Reske, et al., 2007). In the current study, each restaurant was inspected twice before the announced inspections were initiated, and twice after to account for temporal trends. FDA standardized inspectors were used for all post-intervention inspections. Statistical methods were used which accounted for the repeated-measures design. Finally the effects on specific, relevant critical violations allowed us to assess the impacts on different kinds of food safety practices.

The impact on only some types of violations is of particular interest. Reductions in personal hygiene and equipment cleanliness violations may be due to the relative ease in correcting these violations immediately prior to inspection. Avoiding violations in “Hygiene Practices” is accomplished by using gloves, removing personal items from the food preparation area and correctly washing hands. Equipment cleanliness issues may be resolved quickly by having employees clean their work areas immediately prior to the inspection. Holding temperature, cross-contamination problems and sanitizer concentration violations may require more long-term efforts such as equipment monitoring, or repair and food storage reorganization.

Oriental food restaurants were more likely to receive a citation in cross-contamination violations compared to American food establishments. This may reflect an inherent difficulty when using buffet-style serving, and/or may reflect a heightened awareness and precaution on the part of the inspectors. This result may indicate a need for additional attention and training in these facilities.

Kitchens visible from the dining area were less likely to be cited for cross-contamination violations compared to closed kitchens, but none of the other violations

had significant associations in this study. Other studies of restaurant owners and patrons of restaurants with visible kitchens concluded the majority believe open kitchens are more hygienic and cleaner than closed or nonvisible kitchens (Alonso & O'Neill, 2010; Chow, Alonso, Douglas, & O'Neill, 2010). A logical extension would be the expectation that equipment cleanliness violations would be less frequent in open kitchens, however this study did not find an association between the two variables.

Many other factors may have affected the results of this study, but could not be included due a lack of data including time of day that the inspection was conducted, presence of a certified kitchen manager, inspector bias, and management attitudes toward food safety.

The results of this study indicate advantages in implementing announced restaurant inspections. It appears restaurant personnel addressed obvious and easily correctable issues prior to an announced inspection (personal hygiene and equipment cleanliness), but failed to address those violations which were not immediately visible. Future studies may examine ways to improve the effect of announced inspections on less visible critical violations such as specifying violations on which the inspector will focus. It is unknown if the announced inspections have a long term association with reduced critical violations. Additional assessments in future studies may provide information regarding sustained effects. Announced inspections may be useful in addressing problems within violating restaurants to promote behavior change related to specific violations.

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CHAPTER 4

THE EFFECT OF FOLLOW-UP INSPECTIONS ON CRITICAL VIOLATIONS

Abstract

Follow-up inspections are recommended by the FDA as a tool to verify corrections to violations cited during restaurant inspections. There are no published studies that have examined the effect of follow-up inspections on subsequent inspection results. The purpose of this study is to assess whether a serious violation which leads to a follow-up inspection reduces the probability of specific critical violations occurring during the next routine inspection. This study was a retrospective analysis of restaurant inspection results conducted by the Salt Lake Valley Health District between January 1, 2008 through April 1, 2011. There were a total of 5255 routine and follow-up inspections conducted at 1322 restaurants during the study period. Outcome measures were citations for poor personal hygiene, improper holding temperatures, substandard equipment cleanliness, potential cross contamination, and improper sanitizer concentration.

Comparisons of the proportion of inspections during which each of the five outcome critical violations occurred were compared based on whether the restaurant had been subject to a follow-up inspection immediately prior to the inspection or not. Comparisons were also made distinguishing those restaurants where there had been a

critical violation during the routine inspection that lead to the follow-up inspection, and whether this critical violation was of the same type as the outcome critical violation.

Multivariate logistic regression models were used to assess the relationship between the occurrence of a follow-up inspection on the odds of a specific critical violation during the subsequent routine inspection, controlling for other factors thought to be associated with the outcome measures. Covariates included restaurant type, season and inspector experience. For each of the five critical violations assessed, the proportion of inspections with that violation was greater among those restaurants which had a previous follow-up inspection as compared to those inspections that did not have a previous follow-up inspection (range of difference = 6.98% – 22.46%). The risk of having a violation increased for all targeted critical violations during inspections conducted after a follow-up inspection compared to restaurant inspections without a prior follow-up, when adjusting for restaurant type, inspector experience and season. The adjusted odds ratios were significant for all target violations (aOR range = 1.67 – 1.96) with the largest ORs associated with personal hygiene violations (aOR = 1.96, $p < 0.001$).

Introduction

Periodic inspection of restaurants is a key strategy to ensure safe food handling procedures are carried out by commercial food establishments. As specified in the Voluntary National Retail Food Regulatory Program Standards, if inspectors find conditions that pose and imminent health hazard (lack of water, sewage backed up, inability to hold food at proper temperatures, lack of hand-washing facilities, etc.) they must immediately close the restaurant, and not allow the establishment to resume

business until they have been subject to a follow-up inspection to document that all deficiencies have been corrected (U.S Food and Drug Administration, 2011). The establishment may also be closed if there are other critical violations that cannot be resolved during the inspection. These standards have been adopted by at least 46 of the 56 states and territories (U.S. Food and Drug Administration, 2009).

In addition to the closure for imminent health hazard requirement, the Salt Lake Valley Health Department (SLVHD) Food Program Guidelines, in accordance with FDA recommendations, include a requirement that inspectors conduct a follow-up inspection if a restaurant is cited for multiple nonimminent critical violations (Salt Lake Valley Health Department Bureau of Food Protection, 2011). These violations include, but are not limited to inadequate knowledge as demonstrated by excessive violations and the, inability to properly wash and sanitize equipment and utensils. The process of determining whether a restaurant should be reinspected is illustrated in Figure 4.1.

The Food and Drug Administration (FDA) believes that follow-up inspections are a necessary component for reducing the occurrence of foodborne illness risk factors. Standard 6 of the Voluntary National Retail Food Regulatory Program Standards, which is intended to focus regulatory agencies' activities on controlling foodborne illness risk factors, states enforcement activities should "result in follow-up actions for out-of-control risk factors and timely correction of code violations." However, there are no published studies that have examined the effect of follow-up inspections on subsequent inspection results. The purpose of this study is to assess whether a serious violation which leads to a follow-up inspection reduces the probability of specific critical violations occurring during the next routine inspection.

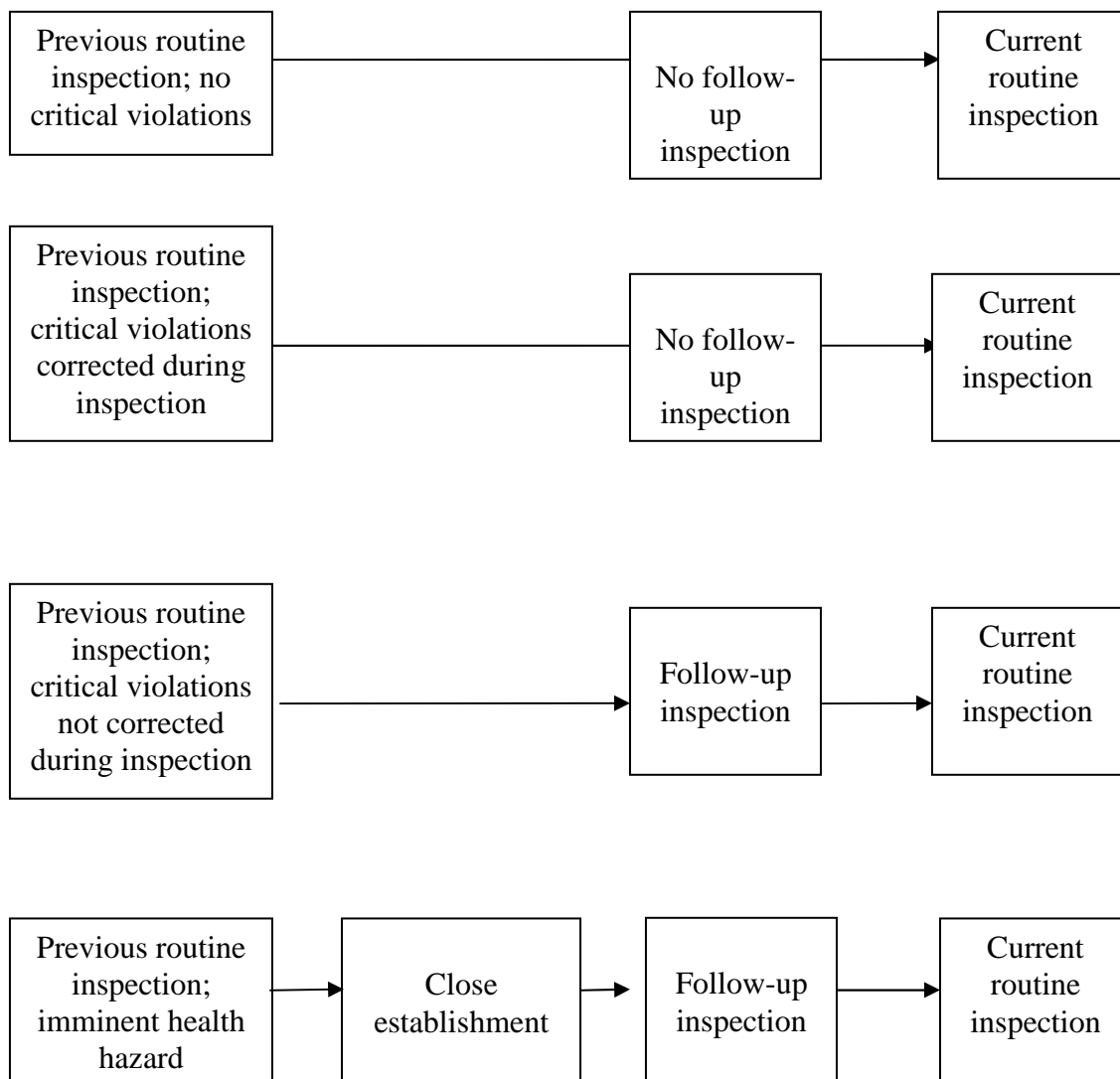


Figure 4.1 Follow-up inspection flow chart

A search of PubMed and EBSCOhost Web Databases returned no published studies that have examined the effect of closures on subsequent inspection results. The purpose of this study is to assess whether a serious violation which leads to a follow-up inspection reduces the probability of specific critical violations occurring during the next routine inspection.

Methods

Study Design

This is a retrospective analysis of restaurant inspection results conducted by the Salt Lake Valley Health Department between January 1, 2008 and April 1, 2011. The study was limited to fast food and full service restaurants which comprise almost 75% of the restaurants in Salt Lake County. Other restaurant types include smaller, low risk establishments (convenience stores, pizza shops, snow cone shacks, etc.) which do not have the processes, menus and procedures generally found in fast food and full service restaurants. There were a total of 5,255 routine and follow-up inspections conducted at 1,322 restaurants during the study period.

Outcome Measures

In this study the outcome measures were citations for five specific critical violations during an inspection. The five critical violations used were poor personal hygiene, improper holding temperatures, poor food contact equipment cleanliness, protection from cross-contamination, and improper sanitizer concentration. These specific critical violations were chosen because they are the five most frequently cited

critical violations in Salt Lake County. The use of critical violations in lieu of foodborne illness cases as a national performance measure to assess compliance with the food code has been recommended by the FDA (U.S. Food and Drug Administration, 2000).

Statistical Analysis

Comparisons of the proportion of inspections during which each of the five outcome critical violations occurred were compared based on whether the restaurant had been subject to a follow-up inspection immediately prior to the inspection or not (Figure 4.1). Comparisons were also made distinguishing those restaurants where there had been a critical violation during the routine inspection that led to the follow-up inspection, and whether this critical violation was of the same type as the outcome critical violation.

Multivariate logistic regression models were used to assess the relationship between the occurrence of a follow-up inspection on the odds of a specific critical violation during the subsequent routine inspection, controlling for other factors thought to be associated with the outcome measures. Odds ratios were used to describe the effect of the follow-up inspection in reducing the occurrence of critical violations.

The covariates included restaurant type, season and inspector experience. Restaurant type delineated fast service and full service restaurants. Season was described as winter (December, January, February), spring (March, April, May), summer (June, July, August), and fall (September, October, November). An “experienced inspector” was defined as an inspector with more than a year of experience. As such a given inspector may have been categorized as “inexperienced” for inspections conducted early in the study and “experienced” for inspections late in the study. The majority of the inspections (89%) were conducted by experienced environmental health scientists.

Two model specifications were used in the analysis. In the first model specification (Model Specification 1), the effect of having a follow-up inspection for any reason was used as the primary risk factor. The second model specification used a three-level variable as the primary risk factor. In this scheme each inspection was classified as: 1) no preceding follow-up inspection (referent group); 2) preceding follow-up inspection where there was not a critical violation of the same type as the dependent variable during the routine inspection that lead to the follow-up inspection; and 3) preceding follow-up inspection where there was a critical violation of the same type as the dependent variable during the routine inspection that lead to the follow-up inspection.

A generalized estimating equation (GEE) estimator with a first order autoregressive (AR1) correlation structure was utilized to account for any correlation between the inspections conducted at individual restaurants. A comparison of correlation structures determined the AR1 structure performed as well as other correlation structures. Data were analyzed using STATA software version 9 (College Station, Texas).

Results

Of the 5,255 routine inspections used in this analysis, 5.0% ($n=263$) were preceded by a follow-up inspection (Table 4.1). The number of fast food restaurants was approximately twice the number of full service establishments. The percentage of inspections conducted in summer was lower than other seasons and the majority of inspections were conducted by experienced inspectors.

The percentages of inspections with and without matching violations cited during the inspection which led to the follow-up and the inspection subsequent to the follow-up

are listed in Table 4.2. The “Yes” category includes the number of inspections with matching violations cited during inspections conducted immediately before and after the follow-up inspection. The “Yes” category does not imply that all of the inspections counted were cited in the inspection conducted before the follow-up inspection. If the violation was not cited during inspections conducted before and after the follow-up, the inspection was counted in the “No” category. Holding temperature and equipment cleanliness violations had a larger percentage of inspections in which those violations were cited during inspections conducted before and after the follow-up compared to those without matching violations.

In the multivariable models, the risk of having a violation increased for all targeted critical violations during inspections conducted after a follow-up inspection compared to restaurant inspections without a prior follow-up, when adjusting for restaurant type, inspector experience and season (Table 4.3). The adjusted odds ratios were significant for all target violations (aOR range = 1.67–1.96) with the largest ORs associated with personal hygiene violations (aOR = 1.96, $p < 0.001$).

Compared to fast food restaurants, full service restaurants were 1.4 times to 2 times more likely to have violations in all of the targeted areas after a follow-up inspection. Inspector experience and season were not significantly different in any of the violations with the exception of sanitizer concentration violations cited in fall compared to winter (aOR = 0.71, $p = 0.03$).

Table 4.1. Inspection distribution by independent variable, number and percentage

Variable	Previous Follow-up Inspection		Total <i>n</i>
	Y <i>n</i> (%)	N <i>n</i> (%)	
Critical Violation			
Holding Temperature	135 (8.6)	1,141 (91.4)	1,576
Personal Hygiene	111 (8.6)	1,178 (91.4)	1,289
Equip. Cleanliness	121 (8.0)	1,391 (92.0)	1,512
Cross-contamination	59 (9.2)	586 (90.8)	645
Sanitizer Concentration	37 (9.5)	354 (90.5)	391
Restaurant Type			
Fast Food Restaurant	164 (4.7)	3,313 (95.3)	3,477
Full Service Restaurant	99 (5.6)	1,679 (94.4)	1,778
Season			
Winter	83 (5.0)	1,572 (95.0)	1,655
Spring	71 (4.9)	1,384 (95.1)	1,455
Summer	46 (4.8)	921 (95.2)	967
Fall	63 (5.4)	1,115 (94.6)	1,178
Inspector Experience			
Inexperienced	32 (5.4)	561 (94.6)	593
Experienced	231 (5.0)	4,431 (95.0)	4,662

Table 4.2 Percentage of inspections with and without matching violations in inspections conducted before and after a follow-up inspection

Group	Number	Percentage
No Previous Follow-up Inspection	4,992	95.0
Holding Temperature Violation in Inspections Before and After Follow-up?		
Yes	179	3.4
No	84	1.6
Personal Hygiene Violation in Inspections Before and After Follow-up?		
Yes	109	2.1
No	154	2.9
Equipment Cleanliness in Inspections Before and After Follow-up?		
Yes	152	2.9
No	111	2.1
Cross-contamination Violation in Inspections Before and After Follow-up?		
Yes	63	1.2
No	200	3.8
Sanitizer Concentration Violation in Inspections Before and After Follow-up?		
Yes	45	0.9
No	218	4.1

Table 4.3 The effect of follow-up inspection results on specific critical violations by before and after follow-up, restaurant type, season and inspector experience

	Holding Temperature aOR (p-value)	Personal Hygiene aOR (p-value)	Equipment Cleanliness aOR (p-value)	Cross Contamination aOR (p-value)	Sanitizer Concentration aOR (p-value)
<u>Model Specification 1</u>					
Previous Follow-up Inspection (No = Referent)	1.83 (<0.001)	1.96 (0.00)	1.67 (<0.001)	1.68 (<0.001)	1.92 (<0.001)
Fast Food vs. Full Service Restaurant (Fast Service = Referent)	1.96 (<0.001)	1.59 (<0.001)	1.45 (<0.001)	1.39 (<0.001)	1.56 (<0.001)
Experienced Inspector (No = Referent)	0.93 (0.49)	1.00 (0.99)	0.95 (0.60)	1.08 (0.57)	1.12 (0.53)
Season (Winter = Referent)					
Spring	0.93 (0.33)	1.00 (0.97)	0.91 (0.24)	0.97 (0.79)	0.97 (0.81)
Summer	0.93 (0.41)	0.99 (0.90)	1.09 (0.31)	0.94 (0.61)	1.07 (0.65)
Fall	0.87 (0.10)	0.91 (0.31)	0.88 (0.12)	0.95 (0.63)	0.71 (0.03)
<u>Model Specification 2</u>					
Without Matching Violations Before and After Follow-up (No Follow-up = Referent)	1.67 (0.02)	1.88 (<0.001)	1.45 (0.06)	1.60 (0.01)	1.62 (0.03)
With Matching Violations Before and After Follow-up (No Follow-up = Referent)	1.91 (<0.001)	2.07 (<0.001)	1.85 (<0.001)	1.90 (0.04)	3.42 (<0.001)
Fast Food vs. Full Service Restaurant (Fast Service = Referent)	1.95 (<0.001)	1.59 (<0.001)	1.45 (<0.001)	1.40 (<0.001)	1.56 (<0.001)
Experienced Inspector (No = Referent)	0.93 (0.45)	1.01 (0.94)	0.95 (0.60)	1.80 (0.59)	1.12 (0.55)
Season (Winter = Referent)					
Spring	0.93 (0.33)	1.00 (0.96)	0.91 (0.23)	0.97 (0.75)	0.97 (0.84)
Summer	0.93 (0.38)	0.98 (0.87)	1.09 (0.32)	0.94 (0.57)	1.07 (0.64)
Fall	0.87 (0.10)	0.92 (0.31)	0.88 (0.11)	0.94 (0.60)	0.72 (0.03)

In the violation-specific models (Model Specification 2), there were increased odds of each violation if the same violations were cited in the inspection which resulted in a follow-up inspection (aOR range = 1.85–3.42). There were also increased odds of each targeted violation if the same violations were not cited during inspections conducted before and after the follow-up inspection (aOR range = 1.45–1.88), although the odds were lower than if the same violations were cited. The remaining results were essentially the same as the first set of models: full service establishments were more likely to be cited for the targeted violations, while the other factors were not significantly associated with the occurrence of the violation. As in the first set of models, however, sanitizer concentration violations were significantly lower in inspections conducted in the fall compared to winter (aOR = 0.72, $p=0.03$).

Discussion

Having been subject to the most severe consequences resulting from poor food safety practices (i.e., closure, fines) does not appear to be a deterrent for poor food safety practices in the future. In fact, for each critical violation studied, the frequency of critical violations cited by inspectors was significantly higher among those restaurants which had received a follow-up inspection after their previous routine inspection.

In the multivariable analysis, the odds ratios for all of the five violations examined in this study indicate nearly a two-fold increase in the odds of being given a critical violation, controlling for restaurant type, season and inspector experience. When considering only those situations where there was a critical violation of the same type as

the outcome measure being considered during the routine inspection that led to the follow-up inspection, the results were the same.

Full service restaurants were significantly more likely to be cited for each of the targeted violations in all model specifications. This effect may be due a number of factors including less complex menus and processes or corporate requirements and training found in some fast service establishments. Season and inspector experience did not appear to affect the results.

To our knowledge this is the first study examining the effect of severe regulatory action on subsequent adherence to food safety regulations. One study conducted in Oklahoma in 2006 examined recurrent critical violations based on restaurant type, local and national chain affiliation and inspector variability (Phillips, Elledge, Basara, Lynch, & Boatright, 2006). The authors concluded recurrent violations were indicative of differences among conditions in the establishments and not inspection practices. The study did not examine the effect of follow-up inspections on critical violations, however.

Many regulatory agencies are trying to find ways to improve food safety, decrease regulatory infractions, and decrease the risk of food borne outbreaks. The results of this study indicate that severe regulatory actions do not act as a deterrent to future poor practices, or have other positive impacts on food safety. Rather, the results seem to indicate that there is a sub-set of establishments that do not practice needed food safety skills, and are not compelled to change their inadequate practices in spite of regulatory action. The management and workers of such restaurants may need more intensive intervention, training or permanent closure, to ensure that food safety standards are met and that the public is protected from deficient food handling practices.

Additional studies may address this issue. SLVHD recently adopted a graduated penalty schedule in which the closure period for critical violations increases with the number of times a restaurant is closed. Revocation of the restaurant permit occurs after the third closure. Future studies will be required to assess the effectiveness of the new penalty schedule. An assessment of restaurant owners and managers' attitudes and active managerial controls may also provide direction for future training and other interventions.

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CHAPTER 5

CONCLUSION

The purpose of this study was to examine the effectiveness of health department interventions and procedures in reducing the occurrence of specific critical violations identified during routine restaurant inspections. Interventions included in the analysis were internet posting of restaurant inspection results, announced routine inspections and follow-up inspections.

In all cases there were very strong and significant associations between the occurrence of critical violations during an inspection and the intervention or procedure, however in some cases the effects were only evident for some of the specific critical violations. In general, the effects of the website implementation and the announced inspections programs yielded the expected results. After the launch of the website the proportion of inspections with a critical violation decreased 20 – 30% depending on the type of critical violation. The announced inspection program also had the desired effect on two of the critical violations; there was a 75% reduction in the odds of an equipment cleanliness violation, and an 84% reduction for personal hygiene violations, controlling for the risk factors. Unexpectedly, there was nearly a 50% reduction in equipment cleanliness violations among the control group as well,

Having had a serious violation that lead to a follow-up inspection did not have the expected effect. Rather than being a learning experience that improves food safety practices, or a deterrent to avoid future sanctions, the odds of receiving a critical violation increased for every critical violation used in this analysis, with odds ratios ranging from 1.67 to 1.96. The extent to which this reflects a sub-population of establishments that need additional attention, or ‘extra attention’ by inspectors during the routine inspections occurring after these serious circumstances remains unclear. In any case, the factors contributing to this consistently poor performance merits serious attention.

Other results may also help indicate the conditions where violations are likely to occur, and where targeted efforts by regulators may lead to greater improvements in food safety. In each analysis, full service restaurants were more likely than fast food establishments to be cited for at least one of the targeted violations. This may be due to the complexity of menu items and processes in full service restaurants and the increased managerial oversight in fast food chain restaurants.

Seasonal effects varied depending on the violation, but the biggest effect was seen in holding temperature and equipment cleanliness violations during summer months compared to all other seasons. The effect of season on holding temperature violations was anticipated due to the increase in refrigeration units in periods of high ambient temperatures. The increase in equipment cleanliness violations during summer months is possibly due to the large influx of part-time summer workers who are not adequately trained in food safety. Season was not a factor in the announced or follow-up studies.

Inexperienced inspectors were more likely to cite all of the targeted violations except for holding temperatures. This effect was unexpected and emphasizes the need for

continued inspector training. Experienced inspectors may also be more willing to not cite a violation if it is corrected during the inspection, especially if the inspector has developed a relationship with restaurant personnel. All of the target inspections may be easily corrected with the exception of holding temperatures in cases where the equipment is malfunctioning.

Regulatory agencies may benefit from the results of this study especially when designing interventions and programs aimed at specific violation types. Announced inspections combined with follow-up inspections may be used to focus managerial attention on specific violations. Posting restaurant inspection results on the internet is an effective method of addressing multiple violations of concern within a jurisdiction. Agencies may explore other programs for long term compliance in addition to follow-up inspections which do not appear to affect inspection results.

Food type and kitchen visibility were only considered in the announced inspection study, but the information gained may be valuable for food inspectors. Both of these factors were evident when evaluating the risk for cross-contamination and sanitizer concentration violations. Additional training in those areas may be warranted in facilities serving Oriental food or visible kitchens.

These programs and procedures were evaluated over a fairly short time duration. An analysis of the long term effects of the website would be beneficial. Announced inspections could be re-evaluated to include a managerial control component. Additional studies examining the relationship between chain restaurants, independent restaurants and critical violations would be beneficial.